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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,667	01/13/2004	Hiroshi Maeda	Q79414	9625

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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,667	MAEDA	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed February 9, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 2, 7-20 and 25-36 have been canceled;
(B) Claims 1, 3 and 21 have been amended;
(C) Comments regarding Office Action have been provided drawn to:
  (I) 102(b) rejection, rendered moot by new ground of rejection over newly cited US Patent;
  (II) 103(a) rejection, rendered moot by new ground of rejection over newly cited US Patent.

2. Claims 1, 3-6 and 21-24 are pending in the case.

3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

4. Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Makuuchi et al (US Patent No. 6,117,815).

Applicants claim a process for producing a saccharide having a lowered molecular weight, which comprises irradiating an electron beam to a polysaccharide fraction in a solid state at a dosage of d(kGy) which satisfies the following equation: $n = Me^{ad}$ wherein M represents a weight average molecular weight (Da) of the polysaccharide fraction and is a number of 5,000 to 70,000; n represents a weight average molecular weight (Da) of the saccharide having a lowered molecular weight and is an optional positive number; e is the base of natural logarithm; and a is a number of –0.008 to –0.004. Additional limitations in the dependent claims include the process wherein the polysaccharide fraction to which the electron beam is irradiated is a glycosaminoglycan fraction.

The Makuuchi et al patent a process wherein sodium alginate in the form of either an aqueous solution or a powder is exposed to a radiation made of γ-rays or electron beams at a dose of 10-500 kGy, whereupon the sodium alginate is

decomposed to produce a low-molecular weight polysaccharide. The amount of dosage disclosed in the Makuuchi et al patent complies with the dosage satisfied by the formula set forth in instant Claims 1, 3 and 4 and the sodium alginate disclosed in the Makuuchi et al patent is a glycosaminoglycan as required in instant Claim 5. The formula, per se, disclosed in Claim 1 was not given weight since the formula does not clearly establish the dosage of electron beam used in the claimed process. The description of the process of producing low-molecular weight polysaccharide by exposing sodium alginate to radiation made of electron beams as disclosed in the Makuuchi et al patent anticipates the instantly claimed process of producing a saccharide having a lowered molecular weight.

Claim Rejections - 35 USC § 103

5. Claims 1, 3-6 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makuuchi et al (US Patent No. 6,117,815) in view of De Ambrosi et al (US Patent No. 4,987,222).

Applicants claim a process for producing a saccharide having a lowered molecular weight, which comprises irradiating an electron beam to a polysaccharide fraction in a solid state at a dosage of d(kGy) which satisfies the following equation: $n = Me^{ad}$ wherein M represents a weight average molecular weight (Da) of the polysaccharide fraction and is a number of 5,000 to 70,000; n represents a weight average molecular weight (Da) of the saccharide having a lowered molecular weight and is an optional positive number; e is the base of natural logarithm; and a is a number of –0.008 to –0.004. Applicants also claim a process for producing hyaluronic acid having lowered molecular weight, which comprises irradiating an electron beam to a hyaluronic acid fraction which has a weight average molecular weight of 600,000 to 1,200,000 (Da) and is in a liquid state at a dosage of 10 to 80 (kGy). Additional limitations in the dependent claims include the process wherein the polysaccharide fraction to which the electron beam is irradiated is a glycosaminoglycan fraction; the process wherein the glycosaminoglycan fraction is a fraction comprising at least one species of glycosaminoglycans selected from the group consisting of hyaluronic acid,

chondroitin sulfate, dermatan sulfate, keratin sulfate, heparan sulfate and heparin; and the process wherein the hyaluronic acid having a lowered molecular weight has a weight average molecular weight of from 1,300 to 4,000 (Da).

The Makuuchi et al patent a process wherein sodium alginate in the form of either an aqueous solution or a powder is exposed to a radiation made of γ-rays or electron beams at a dose of 10-500 kGy, whereupon the sodium alginate is decomposed to produce a low-molecular weight polysaccharide. The Makuuchi et al patent shows that the substitution of procedures that use γ-rays with procedures that use electron beams is within the skill of the artisan. The amount of dosage disclosed in the Makuuchi et al patent complies with the dosage satisfied by the formula set forth in instant Claims 1, 3 and 4. The sodium alginate disclosed in the Makuuchi et al patent is a glycosaminoglycan as required in instant Claim 5. The instantly claimed process of producing a saccharide having lowered molecular weight differs from the process of producing low-molecular weight polysaccharide in the Makuuchi et al patent by claiming a process applicable to specific glycosaminoglycans selected from the group consisting of hyaluronic acid, chondroitin sulfate, dermatan sulfate, keratin sulfate, heparin sulfate and heparin.

The De Ambrosi et al patent discloses a process for the controlled preparation of low molecular weight glucosaminoglycans by treating conventional high molecular weight glucosaminoglycans in the solid state or in solution form with a rectilinear gamma ray beam at doses within the range of 2.5 to 20 Mrad wherein the glucosaminoglycans obtained have a molecular weight of between 1000 and 35,000 Daltons, which meet the requirement of the lowered molecular weight products disclosed in instant Claims 22-24. Also see column 4, last paragraph, wherein the De Ambrosi et al patent suggests that the process thereof is applicable to various glucosaminoglycans such as heparin sulphate, dermatan sulphate, chondroitin-4 sulphate, chondroitin-6 sulphate, hyaluronic acid and alginic acid, which embraces the glycosaminoglycans disclosed in instant Claims 6 and 21-24.

One having ordinary skill in the art would have been motivated to combine the teachings of the Makuuchi et al patent with the teachings of the De Ambrosi et al patent

since both patents disclose lowing the molecular weight of glycosaminoglycans via irradiation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the alginate used in the process for producing a saccharide having lowered molecular weight of the Makuuchi et al patent with other glycosaminoglycans such as heparin sulphate, dermatan sulphate, chondroitin-4 sulphate, chondroitin-6 sulphate, and hyaluronic acid in view of the recognition in the art, as evidenced by the De Ambrosi et al patent, that use of gamma ray beams is an effective procedure for lowing the molecular weight of various types of glycosamino-glycans.

Summary

6. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600